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10/539,421	06/20/2005	Hideaki Yamaoka	10921.0333USWO	1084
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DIETERLE, JENNIFER M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,421

Applicant(s)

YAMAOKA, HIDEAKI

Examiner

Jennifer Dieterle

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/11/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 7-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 7-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

Claims 2, 3, 5 and 6 have been canceled.

Claim 19 has been added by amended.

Claims 1, 4 and 7-19 are being addressed in this action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/10 has been entered.

Comments

1. The rejection of claims 1, 4 and 7-18 under 35 U.S.C. 112, first paragraph have been overcome by Applicant's amendments thereof.
2. The rejection of claims 1, 4 and 7-18 under 35 U.S.C. 112, second paragraph have been overcome by Applicant's amendments thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1, 4, 7, 8, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Gotoh et al. (U.S. Pat. No. 6,071,391) in view of Hodges (WO 2003/032411) or Heller (US 6,143,164).

Regarding claims 1, 4 and 19, Gotoh et al. teaches a thin analysis tool for measuring glucose comprising:

- a first plate 2 formed with a first 3 and second 4 electrodes (figure 15, col. 1, lines 62-63; col. 16, lines 33-35);
- a second plate facing the first and second electrodes of the first plate (col. 1, lines 59-67);

- a reaction space for holding a sample liquid 5 (figure 15);
- a reagent portion that dissolves when the sample is held in the space (col. 14, lines 45-60); the first and second surfaces face each other (col. 17, lines 17-19) spaced at a distance;
- a voltage is applied between the electrodes to facilitate the redox reaction which will inherently create a region around the electrode in which electrons are released (col. 15, line 62).

While Gotoh et al. does not specifically utilize the term "electron release region", it is well known in the glucose sensor art that a glucose sensor basic function is to supply a current and when the reduction mediator comes within a range of the working electrode it releases electrons and the reaction based on the mediator allows for the measurement of the concentration of the analyte of interest (Applicants' specification at paragraph [0004] discusses background art disclosing the basic known function of a glucose sensor). Therefore, to be operational, Gotoh has an "electron release" region as do all glucose sensors.

While Gotoh et al. does teach a reaction space, Gotoh et al. does not specifically teach that the reaction space is no greater than the thickness of the electron release region. Specifically, the facing distance is between 25 and 45 micrometers (claim 4).

Hodges teaches an electrochemical sensor comprising multiple electrodes and a mediator for the determination of analyte (glucose) in a sample (page 3, lines 13-20;

figure 2). Hodges teaches a spacer layer 60 and this layer can be placed sufficiently close to electrodes 52 and 54 such that the closest edges of electrodes 52 and 54 are maintained at less than 500 micrometers apart, preferably less than about 450, 400, 350, 300, or 250 micrometers apart, more preferably less than about 200, 150, or 100 micrometers apart, and most preferably less than about 90, 80, 70, 60, 50, **40, 30, 25, 20**, 15, 10, 5 or 1 **micrometers** (col. 7, lines 28-45). Additionally, one or both of electrodes 52 and 54 may be placed on an additional layer. The spacing being selected to maintain the separation of the electrodes, thereby providing a sample reservoir in the electrochemical cell that has a smaller volume of space which facilitates a corresponding higher amplification factor (page 7, lines 28-31). The facing distance in Hodges is between the upper substrate/spacer and the electrodes (see figure 2) and can be optimized by spacer layer 60 being placed within 1 micrometer of the electrodes which would make the facing distance between the upper surface and the electrode surface being no greater than the thickness of the electron release region.

Heller et al. also teach a small volume electrochemical sensor for the determination of glucose (abstract). Heller et al. teach a measurement zone is contained within this sample chamber and is the region of the sample chamber that contains only that portion of the sample that is interrogated during the analyte assay. (col. 9, lines 62-67). Heller et al. teach that the measurement zone is less than preferably about **0.05 mm (50 micrometers)**(col. 10, lines 50-54). Heller et al. teach that a small reaction chamber is preferable because the thickness is small to promote

rapid electrolysis of the analyte, as more of the sample will be in contact with the electrode surface for a given sample volume. In addition, a thin sample chamber helps to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time. (col. 10, lines 38-54).

Therefore, it would have been obvious to one skilled in the art to modify the reaction chamber size of Gotoh et al. so that the reaction space is no greater than the thickness of the electron release region, specifically between 25 and 45 micrometers, as taught by Hodges or Heller et al. because a smaller volume of space which facilitates a corresponding higher amplification factor (Hodges page 7, lines 28-31) and a smaller chamber will help to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time. (Heller et al. col. 10, lines 38-54).

Additionally, in view of Gotoh's et al. general description (see col. 3, lines 39-44) of the distance between the surfaces being 100 μ m - 500 μ m, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). As taught above by Heller et al. and

Hodges, it is well known in the art to select/optimize a reaction chamber size based on the desire to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time (Heller et al. col. 10, lines 38-54) or to use a smaller volume of space which facilitates a corresponding higher amplification factor (Hodges page 7, lines 28-31) depending on the outcome desired.

Therefore, it would have been obvious to a person of ordinary skill in the art to select an appropriate distance between the electrodes of Gotoh et al. to establish the size of the reaction chamber.

With regard to claim 19, the facing distance spacing that causes diffusion of the electron transport mediator into the electron release region is the intended use of the sensor and the facing distance which is a recitation of the intended use of the claimed invention. It must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art as described above is capable of performing the intended use. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

Regarding claim 7, Gotoh et al. teaches a thin analyzing device but does not expressly teach the use of capillary force to move the sample.

However, it is well known in the glucose sensor art that analyte in a glucose sensor is moved by capillary force. Heller et al. teach that either capillary action is the

known way to move analyte in a sensor and also teach that a sorbent material can be used to facilitate the uptake of small volume samples by a wicking action and may complement (or even replace) the capillary action of the sample chamber (col. 10, lines 55-60).

Hodges teaches that a sample to be admitted to the sensor can be drawn in by wicking or capillary action (page 10, lines 23-24).

Therefore, it would have been obvious to one of ordinary skill in the art to that the analyte in Gotoh et al. is moved by capillary forces as taught by Heller et al. or Hodges because capillary force provides for the movement of fluid into a sensor and the force may even be further enhanced by the use of sorbent material.

Regarding claim 8, Gotoh et al. teaches that the reagent portion includes an electron mediator and a redox enzyme (col. 4, lines 6-16).

Regarding claim 12, Gotoh et al. teaches that the redox enzyme has glucose dehydrogenation activity (col. 7, lines 11-13).

Regarding claim 18, Gotoh et al. teach thin analysis tool for measuring glucose (col. 1, lines 38-40). Gotoh et al. teach the device can be used for the measuring of blood sugar or urine (col. 13, lines 44-46).

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. and Hodges (WO 2003/032411) or Heller (US 6,143,164), as applied to claims 1 and 8 above, in further view of Leong et al. (U.S. Pat. No. 6,837,988).

Regarding claim 9, Gotoh et al. teaches a thin analyzing device, but does not teach the use of ruthenium as the electron mediator.

Leong et al. recognizes that a ruthenium compound can be used as a mediator agent (col. 11, lines 50-60).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). The simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143 B)

Therefore, it would have been obvious to one of ordinary skill in the art to have substituted the known functionally equivalent ruthenium compound taught by Leong et al. for the electron mediator of Gotoh et al. because Loeng et al. shows that either ruthenium complexes or ferricyanide may be utilized as mediator agents (col. 11, lines 50-60).

5. Claims 10, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. and Hodges (WO 2003/032411) or Heller (US

6,143,164) and Leong et al., in view of Nagakawa et al. (WO 03/025558, with reference to it English equivalent, U.S. Pat. No. 7,390,391).

Regarding claims 10, 11 and 13-17, Gotoh et al. teach a thin analyzing device, but do not teach that the X in the ruthenium compound could be NH_3 , a halogen ion, CN, pyridine, nicotinamide, or H_2O and that n^+ is the valence of an oxidized Ru(III) complex determined by a type of X. In addition, Gotoh et al. do not teach that the molecular weight of cytochrome C is about 43 kDa and the subunit of glucose dehydrogenase has a molecular weight of about 60 kDa measured by SDS-polyacrylamide gel electrophoresis.

Nagakawa et al. teach that a ruthenium compound could be NH_3 or a halogen ion (col. 3, lines 63-67; col. 4, lines 1-4). Nagakawa et al. also teach that the microbe may belong to the Burkholderia genus (col. 4, line 57). In addition, Nagakawa et al. teach that the molecular weight of cytochrome C is about 43 kDa (col. 4, lines 43-45) and the molecular weight of GDH is about 60 kDa (col. 4, lines 38-39). Nagakawa et al. teach that the new materials reduced background current (col. 2, lines 62-65).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR*

International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have modified the electron mediator and enzyme of Gotoh et al. to be a ruthenium compound where X is NH₃ or a halogen ion (belonging to the genus Burkholderia) having the molecular weight of cytochrome C is about 43 kDa and the molecular weight of GDH is about 60 kDa as taught by Nagakawa et al. because the new materials reduced background current (col. 2, lines 62-65).

Response to Arguments

Applicant's arguments with respect to claims 1, 4 and 7-18, filed 6/9/2009, have been fully considered but they are not persuasive.

6. Applicant's response that Gotoh (US 6,071,391) is silent in regards to an electron release region is unpersuasive. It is well known in the glucose sensor art that a glucose sensor basic function is to supply a current and when the reduction mediator comes within a range of the working electrode it releases electrons and the reaction based on the mediator allows for the measurement of the concentration of the analyte of interest (Applicants' specification paragraph [0004] discusses background art disclosing the basic known function of a glucose sensor). Therefore, to be operational, Gotoh inherently has an "electron release" region as do all glucose sensors including those of Hodges and Heller.

7. With regard to Applicants' argument concerning Hodges being silent as to a thickness of the electron release region above electrode 32, applicant is directed to the rejection above and that electrodes 52 and 54, as stated above, which are located on the same plane, have an electron release region above these electrodes that can be less than 45 micrometers. With regard to Applicants' argument that Heller, col. 10, lines 38-54, teaches diffusion into a measurement zone, while analyte may enter through diffusion, this section also teach that the thickness (i.e. height or spacing between the first and second regions) is preferably less than 0.05mm as noted above in the rejection of claim 1.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-

7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JMD
2/17/10